

Monitoring of Children on Antiretroviral Therapy (Updated August 11, 2011)

Panel's Recommendations

- Within 1-2 weeks of starting a new antiretroviral (ARV) regimen, children should be evaluated to screen for clinical side effects and to ensure patient/caretaker adherence to the regimen **(AIII)**. Evaluations can be conducted in person or over the phone.
- Following initiation or change in therapy, more frequent evaluation may be needed to support adherence to the regimen **(AIII)**.
- At least every 3-4 months thereafter, children should have a monitoring evaluation to assess both effectiveness and potential toxicity of their ARV regimens **(AII*)**.

Children who initiate antiretroviral therapy (ART) or who change to a new regimen should be followed to assess effectiveness, tolerability, and side effects of the regimen and to evaluate medication adherence. Frequent patient visits and intensive follow-up during the initial months after a new ARV regimen is started are necessary to support and educate the family. The first few weeks of ART can be particularly difficult for children and their caregivers. They must adjust their schedules to allow for consistent and routine administration of medication doses. Children may also experience side effects of medications, and the child and caregivers need assistance in determining whether the effects are temporary and can be tolerated or whether they are more serious or long-term and necessitate a visit to the clinician. Thus, it is prudent for the clinician to assess the child within 1–2 weeks of initiating therapy, either in person or with a phone call, to assure proper administration of medications and to evaluate clinical concerns. Many clinicians will plan additional contact (in person or over the telephone) with the child and caregivers during the first few weeks of therapy to support adherence. It is critical that providers speak to caregivers and children in a supportive manner using layman's terms. This will allow for honest report(s) and ensure dialogue between the provider and both the child and the caregiver(s), even with those who report inconsistent medication adherence.

Baseline laboratory assessments including CD4 count/percentage and HIV RNA level, complete blood count (CBC) and differential, serum chemistries (including electrolytes, blood urea nitrogen [BUN], creatinine, glucose, hepatic transaminases, calcium, and phosphorus), **urinalysis (UA)**, and serum lipid evaluation (cholesterol, triglycerides [TGs]) should be done before initiation of therapy. **In addition, a baseline assessment of ARV resistance using a genotype assay is recommended (see [Antiretroviral Resistance Testing](#)).** Within 4–8 weeks after initiating or changing therapy, the child should be seen to obtain a clinical history, with focus on potential adverse effects of ARVs and adherence to medications; to receive a physical examination; and to receive laboratory tests to evaluate the effectiveness of therapy (CD4 count/percentage, HIV RNA test) and to detect medication-related toxicities. **At a minimum, laboratory assessments should include a CBC and differential, serum chemistries, and assessments of renal and hepatic function.** Following a change in therapy, more frequent evaluation may be needed to support adherence to the regimen. Assessment of initial virologic response to therapy is important because an initial decrease in HIV viral load in response to ART should be observed after 4–8 weeks of therapy.

Subsequently, children taking ARV medication should have assessments of medication adherence and regimen toxicity and effectiveness at least every 3–4 months. **For children and youth who are adherent to therapy with sustained viral suppression and stable clinical status for more than 2–3 years, some experts monitor CD4 counts and HIV RNA levels less frequently.** [Table 15](#) provides one proposed monitor-

Table 15. Example of Minimum Schedule for Monitoring of Children on Antiretroviral Therapy

	Entry into care	Monitoring Pre-Therapy¹	ART Initiation¹	1-2 Weeks on Therapy²	4-8 Weeks on Therapy	Every 3-4 months³	Every 6-12 months	ARV Switch
Clinical History Physical Exam ²	X	X	X	X	X	X	X	X
CBC w differential	X	X	X		X	X		X
Chemistries ⁴	X		X		X ⁴	X		X
Electrolytes	X		X			X		X
Glucose	X		X			X		X
AST/ALT	X	X	X	X ⁵	X ⁵	X		X
Bilirubin	X		X			X		X
BUN/ Creatinine	X	X	X			X		X
Albumin/ Total Protein	X		X				X	X
Ca/ Phosphate	X		X				X	X
CD4 count/%	X	X	X		X ⁶	X		X
HIV RNA	X	X	X	X ²	X	X		X
Resistance Testing	X							X
Adherence evaluation			X	X	X	X		X
Lipid panel	X		X				X	
Urinalysis	X		X				X	

¹ In the event that initiation of therapy is within 30-45 days of a Monitoring Pre-Therapy lab result, repeating at initiation may not be necessary.

² Children starting a new antiretroviral regimen should be evaluated in person or by phone within 1 to 2 weeks of starting medication to screen for clinical side effects and to ensure patient adherence to the regimen. Many clinicians will plan additional contacts (in person or by telephone) with the child and caregivers to support adherence during the first few weeks of therapy. Some clinicians also recommend an HIV RNA measurement within the initial weeks of therapy for an early assessment of response/adherence to therapy.

³ For children who are in a stable treatment status (non-detectable HIV RNA and normal CD4 count/% for at least 12 months) many clinicians are considering 6 month intervals between monitoring lab tests. Some clinicians find value in visits every 3 months even when lab testing is not performed (eg to review adherence and update dosing for interim growth).

⁴ Some antiretroviral drugs require a specific schedule frequency based on toxicity profile (eg, nevirapine and tenofovir; see specific antiretroviral agents).

⁵ For children receiving nevirapine, serum transaminase levels should be measured every 2 weeks for the first 4 weeks of therapy, then monthly for 3 months, followed by every 3 to 4 months.

⁶ Some clinicians do not recommend a CD4 cell count/percentage at this time, considering it too early to expect an immunologic response.

ing schedule, which will require adjustment based on the specific therapy the child is receiving. Assessments should include basic hematology, chemistry, CD4 count/percentage, and HIV viral load. Monitoring of drug toxicities should be tailored to the particular medications the child is taking; for example, periodic monitoring of **urinalysis and serum creatinine** may be desirable in children receiving **tenofovir**, or of serum glucose and lipids in patients receiving protease inhibitors (PIs). Children who develop symptoms of toxicity should have appropriate laboratory evaluations (e.g., evaluation of serum lactate in a child receiving nucleoside reverse transcriptase inhibitor [NRTI] drugs who develops symptoms suspicious for lactic acidosis) performed more frequently until the toxicity resolves.

For further details of adverse effects associated with a particular ARV, see [Tables 17a–17l. Antiretroviral Therapy-Associated Adverse Effects and Management Recommendations](#).

Based on accumulated experience with currently available assays, viral suppression is currently defined as an HIV RNA level below the detection limit of the assay used (generally <40–80 copies/mL). This definition of suppression has been much more thoroughly investigated in HIV-infected adults than in HIV-infected children (see Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents¹). Temporary viral load elevations or “blips” between the level of detection and 1,000 copies/mL are often detected in adults (and children) on ART and should not be considered “virologic failure.” For definitions and management of virologic treatment failure, see [Antiretroviral Treatment Failure in Infants, Children, and Adolescents](#).

Reference

1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. 2011:1-166.